

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: ETHICON WAVE 3 CASES LISTED IN EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE OR
TO LIMIT THE OPINIONS AND TESTIMONY OF STEVEN MACLEAN, PH.D., P.E.**

The litigation against Ethicon and Johnson & Johnson concerning their Prolene-based stress urinary incontinence (SUI) and pelvic organ prolapse (POP) products has been ongoing for several years. During this time period, many of the Defendants' employees were deposed, including witnesses designated by the Defendants as witnesses most knowledgeable about certain subject matters, including the subject of *in vivo* Prolene degradation, who were required under the Federal Rules of Civil Procedure – including in particular Fed.R.Civ.P. 30(b)(6) – to provide complete, knowledgeable and binding testimony on behalf of Ethicon and Johnson & Johnson. As one court explained:

The testimony elicited at the Rule 30(b)(6) deposition represents the knowledge of the corporation, not of the individual deponents. The designated witness is 'speaking for the corporation'.... The corporation appears vicariously through its designee. If the persons designated by the corporation do not possess personal knowledge of the matters set out in the deposition notice, the corporation is obligated to prepare the designees so that they may give knowledgeable and binding answers for the corporation.

Spicer v. Universal Forest Products, E. Div., Inc., No. 7:07CV462, 2008 WL 4455854, at *4 (W.D. Va. Oct. 1, 2008) (quoting *United States v. Taylor*, 166 F.R.D. 356 (M.D.N.C. 1996).

In accordance with the requirements of Rule 30(b)(6), the Defendants designated Dr. Thomas Barbolt as its 30(b)(6) corporate designee on the subject of Prolene's ability to degrade *in vivo*. Dr. Barbolt testified numerous times throughout his deposition that Prolene does undergo *in vivo* surface degradation and that Ethicon knew this several years prior to disseminating misinformation to physicians in its labeling which erroneously claimed that the Prolene does not undergo *in vivo* degradation:

Q: Is it Ethicon's position that the antioxidants in the polypropylene Prolene fibers in TVT can leach from the fibers?

A: THE WITNESS: Yes.¹

Q. And could you explain to the ladies and gentlemen of the jury what we mean by "leach"?

A. Leaching means the movement of substances from an implant into the surrounding tissue.²

Q. So you would agree as a spokesperson - - as a 30(b)(6) person for Ethicon that the surface of polymer fibers, including the polypropylene fibers in TVT, can crack?

A. Yes.³

Q. Despite the antioxidants being added to the Prolene sutures, in two of the Prolene sutures in the study, the surface layer was cracked, correct?

A. Two revealed cracking, yes.

Q. **And you aren't suggesting to the ladies and gentlemen of the jury that those cracks were anything other than the Prolene polypropylene, are you?**

¹Exhibit A - Excerpt from the 30(b)(6) Deposition of Dr. Thomas Barbolt, 1/8/2014, at 360:20-25.

²Exhibit A - Excerpt from Barbolt Dep., 1/8/2014, at 361:2-6.

³Exhibit A - Excerpt from Barbolt Dep., 1/8/2014, at 385:14-20.

A. **No, I am not suggesting that,** and that's not reflected in this report.

Q. **You would agree that the surface that's cracked here is the polypropylene surface layer, correct?**

A. In reading the report, it says that – **that's what I would conclude.**⁴

Q. **And that's Ethicon's position as you -- as the spokesperson for Ethicon, it's Ethicon's position that degradation, surface degradation, can occur, correct?**

A. **Yes.**

Q. And this was known well in advance of this statement that the material is not absorbed, nor is it subject to degradation, correct?

A. Yes. This is from 1992.⁵

Thus, Ethicon and Johnson & Johnson are bound by the admissions of its 30(b)(6) corporate designee that their Prolene-based SUI and POP mesh products undergo *in vivo* surface degradation. Nevertheless, the Defendants hired Dr. MacLean in an effort to undo this damaging testimony and, not surprisingly, Dr. MacLean's opinions contradict Dr. Barbolt's testimony. The Defendants should not be permitted to undo testimony of its 30(b)(6) corporate designee simply because they do not like the answers he provided. Courts have refused to allow these types of substantive changes as "To allow these types of corrections would undermine the Rule 30(b)(6) deposition. An interpretation of liberal—indeed unlimited—amendments and corrections would discourage the careful preparation of 30(b)(6) witnesses. Rather than advancing the pursuit of truth in discovery, a policy of liberal "amendments" and "corrections" would encourage and intensify lawyer wordsmithing and parsing." *Wyeth v. Lupin Ltd.*, 252 F.R.D. 295, 297 (D. Md. 2008).

⁴Exhibit A - Excerpt from Barbolt Dep., 1/8/2014, at 396:2-23 (emphasis added).

⁵Exhibit A - Excerpt from Barbolt Dep., 1/8/2014, at 409:2-13 (emphasis added).

Other district courts have reached similarly conclusions. In *Rainey v. American Forest & Paper Ass'n. Inc.*, 26 F. Supp.2d 82, 94 (D.D.C. 1998), the Defendants' designated 30(b)(6) witnesses whose binding testimony failed to create a material issue in dispute. Thus, the plaintiff moved for summary judgment. In response, the Defendants attached an affidavit of a former employee which contradicted the defendant's corporate designees' sworn testimony. Like here, the plaintiff in *Rainey* argued that Rule 30(b)(6) precluded the defendant from developing a new theory of the facts that differs from that articulated by the designated representative. The District Court agreed, precluded the contrary evidence and held that:

Plaintiff's theory is consistent with both the letter and spirit of Rule 30(b)(6). First, the Rule states plainly that persons designated as corporate representatives "shall testify as to matters known or reasonably available to the organization." Fed.R.Civ.P. 30(b)(6). This makes clear that a designee is not simply testifying about matters within his or her own personal knowledge, but rather is "speaking for the corporation" about matters to which the corporation has reasonable access. *United States v. Taylor*, 166 F.R.D. 356, 361 (M.D.N.C.1996), *aff'd* *United States v. Taylor*, 166 F.R.D. 367 (M.D.N.C.1996) (quoting 8A Charles Alan Wright *et al.*, Federal Practice and Procedure, § 2103, at 36–37 (2d ed.1994)). By commissioning the designee as the voice of the corporation, the Rule obligates a corporate party "to prepare its designee to be able to give binding answers" in its behalf. *Ierardi v. Lorillard, Inc.*, 1991 WL 158911, at *3 (E.D.Pa. Aug.13, 1991); *Taylor*, 166 F.R.D. at 361 (designee "presents the corporation's 'position' on the topic") (internal citation omitted). **Unless it can prove that the information was not known or was inaccessible, a corporation cannot later proffer new or different allegations that could have been made at the time of the 30(b)(6) deposition.** See *Ierardi*, 1991 WL 158911, at *3; *Taylor*, 166 F.R.D. at 362.

Id at 94 (emphasis added). This is exactly what the Defendants are attempting to do with Dr. MacLean whose opinions concerning Prolene's propensity to degrade wholly contradicts the binding testimony of Ethicon's corporate representative, Dr. Thomas Barbolt. For this reason alone, Dr. MacLean's opinions should be excluded.

CONCLUSION

Plaintiffs respectfully request that this Court grant their Motion to Exclude the Opinions and Testimony of Dr. Maclean, Ph.D., P.E. which contract the admissions by Dr. Thomas

Barbolt. In particular, Dr. MacLean should be precluded from testifying that Prolene does not undergo *in vivo* surface degradation as the Defendants – through their corporate designee Dr. Barbolt – are bound by Dr. Barbolt’s admission that Prolene undergoes *in vivo* surface degradation.

Dated: Sept. 19, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on Sept. 19, 2016 I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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